

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-780V
UNPUBLISHED

SANDRA FRANCIS,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: December 5, 2022

Special Processing Unit (SPU);
Severity Requirement; Shoulder
Injury Related to Vaccine
Administration (SIRVA)

Edward M. Kraus, Law Offices of Chicago Kent, Chicago, IL, for Petitioner.

Camille Michelle Collett, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION¹

On June 26, 2020, Sandra Francis filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”), alleging that she suffered a shoulder injury related to vaccine administration (“SIRVA”) as a result of an influenza (“flu”) vaccine administered to her on October 27, 2017. Petition, ECF No. 1 at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

For the reasons detailed herein, I find that Petitioner has not satisfied the six-month sequelae requirement. Therefore, Petitioner cannot establish entitlement to compensation, and this matter must be dismissed.

¹ Although I have not formally designated this Decision for publication, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002, because it contains a reasoned explanation for my determination. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

A year and a half after the claim's initiation, Respondent filed his Rule 4(c) Report, arguing that Petitioner could not satisfy the six-month sequelae requirement (or "severity requirement"). ECF No. 26 at 7. To resolve the matter expeditiously, briefs addressing the issue were ordered. ECF No. 27.

On May 2, 2022, Petitioner filed her brief on the severity requirement. ECF No. 28. Petitioner acknowledged a significant treatment gap (as discussed below), but asserted that it was not proof that the alleged SIRVA had resolved within six months of onset. *Id.* at 11. Rather, Petitioner noted that the subsequent records are "replete with numerous recordation that Ms. Francis had been experiencing shoulder pain since October 2017." *Id.* at 12. Respondent maintained that Petitioner's vaccine-related shoulder injury did not persist for six months. ECF No. 31 at 7. Specifically, Respondent noted that Petitioner's right shoulder had improved prior to six months post-vaccination, followed by a sixteen-month period during which she sought no treatment for her right shoulder. *Id.* Respondent further submitted that Petitioner's later pain was likely due to "worsening osteoarthritis, for which there is record evidence." *Id.* at 7-8. Petitioner filed a reply, reiterating that her testimony and records in 2019 satisfy the severity requirement. ECF No. 33.

The matter is now ripe for adjudication.

II. Factual Finding

At issue is whether Petitioner suffered from a shoulder injury for more than six months. Section 11(c)(1)(D)(i) (statutory six-month sequelae requirement).

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Medical records created contemporaneously with

the events they describe are generally considered to be more trustworthy. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Human Servs.*, 993 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that *Cucuras* does not stand for proposition that medical records are presumptively accurate and complete). While not presumed to be complete and accurate, medical records made while seeking treatment are generally afforded more weight than statements made by petitioner after-the-fact. See *Gerami v. Sec'y of Health & Human Servs.*, No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014). Indeed, “where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight.” *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006); see *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948).

However, incomplete or inaccurate medical records may be outweighed by later testimony, if such testimony is “consistent, clear, cogent, and compelling.” *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90- 2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). It is within the special master’s discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational. *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993).

When the severity requirement is in question, Petitioner must show by preponderant evidence that she “suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine.” 42 U.S.C. § 300aa-11(c)(1)(D)(i); see *Song v. Sec'y of Dep't of Health & Human Servs.*, 31 Fed. Cl. 61, 65-66 (1994), *aff'd*, 41 F.3d 1520 (Fed. Cir. 2014) (noting that a petitioner must demonstrate the six-month severity requirement by a preponderance of the evidence). A petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence.” *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Finding that petitioner has met the severity requirement cannot be based on petitioner’s word alone, though a special master need not base their finding on medical records alone. See § 13(a)(1); see *Colon v. Sec'y of Health & Human Servs.*, 156 Fed. Cl. 534, 541 (2021).

B. Analysis

After a review of the entire record, including Respondent's Rule 4 Report and the parties' briefs, I find that Petitioner has not satisfied the six-month sequelae requirement.³ I specifically note the following facts:

- On October 27, 2017, Petitioner received a flu vaccine in her right arm. Ex. 5 at 3-4.
- On November 10, 2017 (two weeks after her vaccination), Petitioner presented to Dr. Ayesha Cheema, an internist, complaining of mild to moderate shoulder pain since her vaccination the prior month. Ex. 1 at 4. Petitioner specifically reported localized pain and slight limitation in range of motion. *Id.* Dr. Cheema found normal muscle mass and good range of motion on examination, and assessed Petitioner with right anterior shoulder pain, with a differential including "arthritis versus other," and prescribed Medrol Dosepak and Tylenol. *Id.* at 5. Petitioner was to follow up with Dr. Cheema in one week. *Id.*
- On December 28, 2017, now two months after vaccination, Petitioner presented to Dr. Lola Torres, an internist, and complained of right shoulder pain since her vaccination. Ex. 11 at 12. She reported that her pain radiated down her arm and across her back. *Id.* Upon examination, Dr. Torres found limited range of motion, tenderness of the anterior shoulder, and positive empty-can test. *Id.* at 14. Dr. Torres assessed Petitioner "likely tendonitis" and "possible partial rotator cuff tear." *Id.* Home exercises and over-the-counter pain medication were recommended, along with imaging and physical therapy if Petitioner's symptoms did not improve. *Id.*
- Petitioner returned to Dr. Torres on January 11, 2018, for her right shoulder pain. Ex. 4 at 6. Petitioner reported mild but improving pain, and Dr. Torres noted that Petitioner's shoulder was "getting better." *Id.* at 8. Under associated symptoms, Dr. Torres noted "no catching/locking...no radiation down arm...weakness (right arm getting better.)" *Id.* Upon examination, "limited ROM...but improved since last visit," was noted. Because Petitioner's condition was gradually improving, Dr. Torres continued to recommend home exercises and over-the-counter pain medication, along with physical therapy and imaging if symptoms did not continue to improve. *Id.*

³ While I have not specifically addressed every medical record, or all arguments presented in the parties' briefs, I have fully considered all records as well as arguments presented by both parties.

- Petitioner called Dr. Torres's clinic on January 30, 2018, requesting a physical therapy referral. Ex. 4 at 10. No follow-up from Petitioner or Dr. Torres's clinic was noted in the medical record submitted, however.
- There is a subsequent gap of almost four months in the medical records, revealing no subsequent treatment. Six months from the late-October vaccination would be on or around the end of April 2018.
- On June 4, 2018, Petitioner presented for Dr. Gabriel Maijub for her annual exam. Ex. 7 at 9. Petitioner reported arthralgias and stiffness – location was not documented *Id.* at 13. Petitioner's musculoskeletal examination was normal aside from "changes consistent with osteoarthritis" involving multiple joints. *Id.* at 11, 14. Petitioner's extremities were normal with "full ROM." *Id.* at 15. Right shoulder pain was not documented, and there is no mention of any vaccine-related injury.
- There is another treatment gap in the record – this one approximately eleven months long. On May 14, 2019, Petitioner presented to Dr. Maijub for a joint pain referral. She ow ncomplained of joint pain "so bad she has occasionally had to take a few of her husband's floricet." Ex. 7 at 3. Petitioner reported arthralgias, joint swelling, neck pain, stiffness, and bilateral hand pain. *Id.* at 6. On examination, Dr. Maijub noted cervical spine pain and tenderness, changes consistent with osteoarthritis, and bilateral swelling of Petitioner's hands. Right shoulder pain was also noted. *Id.* at 7. Dr. Maijub ordered x-rays of Petitioner's neck, hands, and right shoulder. *Id.* Petitioner's x-rays showed advanced degenerative changes in her cervical spine and foraminal stenosis. *Id.* at 27. Moderate-to-advanced osteoarthritic changes in Petitioner's hands and moderate arthritis in her right acromioclavicular joint were noted. *Id.* at 29-30.
- On June 27, 2019, Petitioner presented to Parkersburg Orthopedic Associates for her right shoulder pain. Ex. 9 at 3. Petitioner was seen by Heidi Rusk, PA-C, and Dr. George Herriott III, and she reported that her shoulder pain began after a flu vaccine in October of 2017, which was not helped by OTC medications or a TENS unit. *Id.* Normal active and passive range of motion was noted, though with pain; positive Neer's, negative Hawkins, and negative cross-body testing were also noted. *Id.* at 5. X-rays taken in the office showed degenerative changes in Petitioner's acromioclavicular joint. An MRI was ordered, and a corticosteroid injection and physical therapy referral were offered. *Id.* at 6; Ex. 2 at 7.

- Petitioner underwent a right shoulder MRI on July 3, 2019. Ex. 2 at 4. The MRI showed a distal supraspinatus full thickness tear, joint effusion extending into the subacromial subdeltoid bursa, moderate degenerative osteoarthritis at the acromioclavicular joint, and biceps tendinitis. *Id.* at 13-14. Following the results of the MRI, a rotator cuff surgery was scheduled for August 22, 2019 with Dr. Jeffrey McElroy. *Id.* at 21.
- On July 12, 2019, Petitioner presented to a rheumatologist, Dr. Jonathan Krant, for osteoarthritis management. Ex. 8 at 12, 14. Upon examination, Dr. Krant noted some limitation in right shoulder external rotation as well as nodes in multiple finger joints. *Id.* at 15. Dr. Krant diagnosed Petitioner with primary osteoarthritis and referred Petitioner for orthopedic assessment of her right shoulder. *Id.* at 16.
- Petitioner followed-up with Dr. Krant for her osteoarthritis and osteoporosis on July 30, 2019. Ex. 8 at 3. Petitioner complained of hip pain, osteoarthritic pain, and right shoulder pain due to rotator cuff tear. *Id.* at 5. Petitioner was scheduled for a bone density scan in one year. *Id.*
- On August 19, 2019, Dr. Jeffrey McElroy, Petitioner's orthopedic surgeon, examined Petitioner's right shoulder, reviewed the MRI, and agreed that a surgical repair of Petitioner's rotator cuff and subacromial decompression would be appropriate. Ex. 9 at 10.
- On August 22, 2019, Petitioner underwent right shoulder arthroscopy, arthroscopic subacromial decompression, and rotator cuff repair. Pet. Ex. 9 at 12-13. During a post-operative orthopedic visit on August 29, 2019, it was noted that Petitioner's surgical incision was healing well and Petitioner had full passive range of motion. She was referred to physical therapy. *Id.* at 17.
- On September 4, 2019, Petitioner began physical therapy and attended eight sessions in total. Ex. 6 at 3-16. At her last visit on October 1, 2019, Petitioner pain level was noted to be zero. *Id.* at 16.
- On October 30, 2019, Petitioner followed-up with Dr. Elroy. Ex. 9 at 24. Petitioner reported some sharp pains in her right shoulder. *Id.* Petitioner's right shoulder forward flexion was noted to be 150 degrees. *Id.* at 26. Dr. McElroy recommended Petitioner continue home exercises. *Id.* at 27.

- On August 27, 2020, Petitioner presented for an annual exam during which she had no complaints, and her physical exam was noted as normal. Ex. 13 at 5-8.

In addition to her records, Petitioner filed a personal affidavit in support of her claim. Ex. 12. Petitioner explained that her pain was immediate upon vaccination. *Id.* ¶4. She had difficulty using her arm and “relied on [her] husband for getting dressed.” *Id.* ¶5. Petitioner affirmed that she sought care for her arm in Florida, where she spent the winters with her husband. She presented to doctors in November of 2017, December of 2017, and January of 2018, but was only treated conservatively with home stretching exercises, OTC medication, rest, and ice. *Id.* ¶¶6-8.

At her January 11, 2018 appointment with Dr. Torres, Petitioner affirmed that she was told her pain would improve with time. Ex. 12 at ¶8. Petitioner “trusted in the advice” and “believed that [her] arm pain would improve over time.” *Id.* ¶9. She affirmed that she continued to feel pain and stiffness in her right shoulder and her everyday activities were affected. Once she and her husband returned to their home in West Virginia, she reported her shoulder pain during her annual physical exam in June 2018. *Id.* ¶10. She was told that her shoulder was due to arthritis. *Id.* As such, Petitioner “felt like no one would help.” She “hoped it would simply improve” and “worked to adapt.” *Id.* ¶11.

According to Petitioner, her pain continued – waking her up at night and making everyday activities difficult. She felt she could do nothing but “suffer through it.” *Id.* ¶12. Almost a year later, in May of 2019, Petitioner “could no longer tolerate the pain” and returned to her primary care physician complaining of shoulder pain and stiffness. *Id.* ¶13. Petitioner then learned that an x-ray of her shoulder showed some arthritis, and an MRI showed a rotator cuff tear in her right shoulder. *Id.* ¶¶14,16. In July of 2019, Petitioner received a call from her orthopedist who recommended and scheduled her for surgery to repair her rotator cuff. *Id.* ¶17. Petitioner underwent surgery on August 22, 2019 and attended eight physical therapy sessions. *Id.* ¶¶19-20. Petitioner affirmed that she continues to have difficulty with her right arm, including getting dressed and performing house chores. *Id.* ¶23.

Respondent disputes whether Petitioner’s right shoulder pain in 2019 is associated with Petitioner’s alleged shoulder injury related to her October 2017 vaccination. ECF No. 31 at 7. Respondent specifically notes that Petitioner’s right shoulder pain was gradually improving in January 2018, and then Petitioner did not report or seek care for her right shoulder for sixteen months - assuming the June 2018 treatment event was not intended to address the alleged SIRVA. *Id.* at 7. Respondent specifically notes as well, however, that there is no mention of right shoulder pain in Petitioner’s June 4, 2018 record (the record most contemporaneous to six-months post-vaccination), only “changes consistent

with osteoarthritis.” *Id.* at 3, 7. Respondent further suggests that Petitioner’s right shoulder pain in May 2019 was related to arthritis. *Id.* at 7-8.

Petitioner, however, argues that her shoulder pain never resolved, and that records following the treatment gap consistently indicate that she had been experiencing shoulder pain since October 2017. ECF No. 28 at 12. She also contends that the June 4, 2018 record is not accurate and/or complete—she affirms that she reported her right shoulder pain at that visit. ECF No. 28 at 11; ECF No. 33 at 2. Petitioner alleges that “absence of reference to a condition is much less significant than a reference that negates that condition’s existence,” and “there is nothing in the June 2018 record to negate Ms. Francis’s testimony that she was experiencing right shoulder pain at that time.” ECF No. 28 at 11. Regarding the treatment gaps, Petitioner submits that “this issue is more probative as to the issue of damages if anything.” *Id.*

Despite what Petitioner argues as an “issue of damages if anything,” there are two substantial gaps in the medical record highly relevant to the disputed severity issue. The first gap occurred between three-months and eight-months post-vaccination⁴ - and the initial six month post-onset date would fall in this period. The second gap occurred between eight-months and nineteen-months post-vaccination.⁵

While some compensated petitioners have delayed seeking treatment or intermittently sought treatment, that is not the case here. Petitioner sought treatment for three months (November 2017 – January 2018) and then did not see another physician for *five* months. In addition, unlike cases where a petitioner cannot show treatment close to the six-month “anniversary” (but can show some lingering sequelae later, or treatment a bit after), here Petitioner’s next occasion to visit a physician in June 2018 yielded a record that makes no mention of right shoulder pain. See Ex. 7 at 9-15. Then, an *eleven-month* gap followed. The lengthy gaps in the record reasonably allow for the possibility that *other* intervening issues or factors caused the later symptoms and reports of right shoulder pain in May of 2019, despite Petitioner’s later references to her vaccination.

In addition, Petitioner’s affidavit provides little support for her claim, particularly as it is uncorroborated. While I appreciate Petitioner’s argument that the absence of documented right shoulder pain in the June 2018 medical record does not negate the possibility of such pain, I cannot find the severity requirement satisfied on Petitioner’s word alone. See *Colon v. Sec’y of Health & Human Servs.*, 156 Fed. Cl. 534, 541 (2021). Moreover, I do not find Petitioner’s affirmation cogent or compelling. *If* Petitioner was

⁴ Petitioner sought treatment for her right shoulder on January 11, 2018 and then did not see another physician until June 4, 2018, “for her yearly Medicare physical.” ECF No. 28 at 3; Ex. 4 at 8; Ex. 7 at 9.

⁵ After seeing her primary care physician on June 4, 2018 for her yearly physical, Petitioner did not return for additional treatment until May 14, 2019. Ex. 7 at 3, 9.

suffering from right shoulder pain at her June 2018 visit (and had been suffering from pain that affected her everyday activities for five months without any treatment or resolution), why Petitioner would then again fail to see any physician for another *eleven months* is difficult to understand. Petitioner affirms that she did not seek care because she “felt like no one would help” and that she could do nothing but suffer through it, yet Petitioner did not attend physical therapy, seek out any new physicians, or return to her primary care physician. The record does not indicate any calls for referrals or requests for medication to ease symptoms that allegedly interfered with Petitioner’s everyday activities.

In total, Petitioner did not receive treatment for *sixteen* months. Such a lengthy treatment gap cannot be easily dismissed. Though Petitioner contends that there is nothing in the record that negates her testimony of shoulder pain in June of 2018 or past the six-months mark, I find the record alone does not preponderate despite her testimonial contentions. At bottom, while it is clear Petitioner suffered some sort of shoulder pain following her vaccination and experienced a rotator cuff tear and repair in 2019, there is not preponderant evidence to satisfy the severity requirement.

Conclusion

Based on the entire record, I find that Petitioner has failed to provide preponderant evidence to satisfy the six-month sequelae requirement. **Petitioner’s claim is hereby dismissed.**

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.⁶

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

⁶ Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.